Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 2001

ALLEGRA D. HEMPHILL

Petitioner,

v.

MCNEIL-PPC, INC.,

Respondent.

On Petition for Writ of Certiorari

to the United States Court of Appeals

for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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115pgs

QUESTIONS PRESENTED FOR REVIEW.

1. By the omission of USPTO Examiner's statements regarding the structure in the prior art '567 patent, did the court prejudice claim construction?

2. The term "vaginal swab" has more than one meaning. Should the court construe the term as structural?

3. Claim 2 reads "core member being secured to said housing means". Is the court denying 35 U.S.C.§112 ?

4. For safety and effectiveness reasons, the claim 2 "secures". The specification is ensuring security also. A dictionary definition "attaches". Does extrinsic evidence (dictionary definition) limit the legally operative meaning in the intrinsic evidence (the claim and specification)?

5. Serenity ®is an accused device. The Federal Circuit forgets to construe an element. Will the Supreme Court perform the literal patent infringement analysis for the asserted claim 2, species #4 Fig. 8 and 9 in the '720 patent?

LIST OF PARTIES

[X] All parties appear in the caption of the cover page.

Johnson & Johnson, One Johnson & Johnson Plaza New Brunswick, New Jersey 08933 is the parent company of McNeil-PPC, Inc.

[ ] All parties do not appear in the caption of the case on the cover page. A list of all parties to the proceeding in the court whose judgement is the subject of this petition is as follows:

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United States Department of Commerce

Patents and Trademarks Office

Patent Application Number 619,684

Hemphill United States Letters Patent #4,557,720

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM 2001

PETITION FOR WRIT OF CERTIORARI

to the UNITED STATES COURT OF APPEALS

for the FEDERAL CIRCUIT

Petitioner, respectfully prays that a writ of certiorari issue to review the judgement below.

OPINIONS BELOW

[X] For cases from **federal courts:**

The opinion of the United States court of Appeals for the Federal Circuit appears at Appendix A to the petition and is

[ ] reported at _____; or

[ ] has been designated for publication but is not yet reported; or

[X] unpublished, as of March 8, 2002.

The opinion of the United States district court for the District of Maryland appears at Appendix B and Appendix C to the petition and is

[X] reported at Hemphill v. McNeil-PPC, Inc., 134 F.Supp. 2d. 710 (D. Md. 2001);or,

[ ] has been designated for publication but is not yet

[ ] reported; or is unpublished.

JURISDICTION

[X] For cases from **federal courts:**

The date on which the United States Court of Appeals for the Federal Circuit decided my case was November 27, 2001.

[ ] No petition for rehearing was filed in my case.

[X] A timely petition for rehearing was denied by the United States Court of Appeals for the Federal Circuit on December 21, 2001, and a copy of the order denying rehearing appears at Appendix D.

[ ] An extension of time to file the petition for a writ of certiorari was granted to and including _____(date) on ___(date) in Application No. A-____.

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(l).

On petition for writ of certiorari, the captioned case Hemphill v. McNeil-PPC, Inc., results from a literal patent infringement suit. The United States District court for the District of Maryland presided over jurisdiction pursuant to 28 U.S.C.§ 1338. The decision was on March 12, 2001 and reconsideration was denied on May 11, 2001.

On appeal, in the United States Court of Appeals for the Federal Circuit the decision was on November 27, 2001. Rehearing was denied on December 21, 2001. Jurisdiction in the U.S. Court of Appeals for the Federal Circuit for Hemphill v. McNeil-PPC, Inc., No. 01-1391 was exercised pursuant to 28 U.S.C. §1295(a)(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

A). **35 U.S.C.§ 112 SPECIFICATION,**

SEE Appendix E, pg. 72-73.

("[a]pplicants are now required by 35 U.S.C.§ 112 to particularly point out and distinctly claim the subject matter the applicant regards as his [or her] invention and this requirement applies with equal force to claims having means-plus-function limitations"). Markman v. Westview Instruments, Inc. 52 F.3d. 967 (Fed. Cir 1995) 988.

("Anyone who wants to know what a patent protects must first read its claim, for they are the measure of its scope"). Markman v. Westview Instruments Inc., 52 F. 3d, 967 (Fed. Cir. 1995), on page 990, I.

("The claims of the patent provide the concise formal definition of the invention. They are the

numbered paragraphs which 'particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his [or her] invention'. 35 U.S.C. §112. It is to these wordings that one must look to determine whether there has been infringement."). E.I. DuPont De Nemours & Co. v. Phillips Petro. 849 F2d. 1430 (Fed. Cir 1988), 1433.

B) SEVENTH AMENDMENT RIGHT

The pro se plaintiff's request for jury trial was usurped. Appendix G, pg. 90-93.

("Jury trial in patent cases is protected by Seventh Amendment. Elimination of the jury is not this court's choice to make. The constitutional right alone bars the majority's rule. The majority today denies 200 years of jury trial on patent cases in the United

States,...by simply calling a question of fact a question of law. The Seventh Amendment is not so readily circumvented."). Markman v. Westview Instruments Inc., 52 F. 3d, 967 (Fed. Cir. 1995), on page 1000, at 3.

The Constitution.

STATEMENT OF THE CASE

Petitioner Allegra D. Hemphill ("Hemphill") is the inventor in the United States Letters Patent 4,557,720 ('the 720 patent') dated December 10, 1985. The title of the '720 patent is "Vaginal Applicator". There are two independent claims. Claim 2 is asserted. Claim 2 is structural. Claim 2 entitles a vaginal swab. Claim 2 defines the invention. Col. 7, ll.6 through Col. 8, ll.10. The elected species is #4, Figures 8 and 9, in Col. 5, ll.27 through Col. 6, ll. 58 . See the '720 Patent in Petitioner's Lodging, "PL", pages 401-408.

In 1998, Allegra Hemphill and Johnson & Johnson agreed to terms in claim 2 with no factual dispute. The '720 patent underwent 'reexamination' in the United States Patent and Trademark Office (the "USPTO).[1] The USPTO denied their prior art McNair 4,285,343 Patent (the '343 patent") as not being relevant under 35 U.S.C.§ 102 and not relevant under 35 U.S.C. §103 in April 1998. See Appendix F, pg. 75-77. The USPTO awarded the certificate of patentability to the Hemphill '720 patent over the prior art of Srininvasan et al. 3,973,567 Patent (the '567 patent) on January 26, 1999. See Appendix F, pg. 78-89. Johnson & Johnson did not contest any decision(s) by the USPTO. "There were no amendments...". See Appendix F, pg. 89.

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[1]Johnson & Johnson asserted two prior art patents against the '720 patent which warranted two 'Requests for Reexamination' in the United States Patent and Trademark Office. See Appendix H, 94-106.

("This undisputed public record of proceedings in the Patents and Trademarks Office is of primary significance in understanding claims."). Markman v. Westview Instruments, Inc., 52 F.3d. 967, (Fed. Cir. 1995) 980 at [13-15]. ("As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of claims"). Vitronics Corp. v. Conceptronic, Inc., 90 F. 3d. 1576 (Fed. Cir. 1996) 1582 at [9-11]. ("If the language of a claim is not disputed, then the scope of the claim may be construed as a matter of law."). Markman v. Westview Instruments, Inc., 52 F.3d. 967 (Fed. Cir 1995) 1018, 1019.

The accused devices are Stayfree®, Carefree®, and Serenity®. [2] Johnson & Johnson has a standard

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[2]See Serenity® in PL, pg . 602. See Stayfree® in Pl. pg. 603.

industrial code 2676. Therefore, in the District Court for the District of Maryland, Hemphill sued Johnson & Johnson *One Johnson & Johnson Plaza, New Brunswick, New Jersey* 08933 on March 8, 1999. On June 4, 1999, Defendant Johnson & Johnson Motions before the district court to substitute McNeil-PPC, Inc (SIC 2834) as the official defendant.[3] See Appendix G, pg.90-93.

On February 14, 2000, McNeil-PPC, Inc., was admitted into DKC 99-CV-654 as the official defendant. [4]

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[3]Defendant Johnson & Johnson is "telling" the U.S. District court for the District of Maryland: ("These products are not manufactured or sold by Johnson & Johnson. They are products of a different company called McNeil-PPC, Inc."), See Paper No. 15 filed in DKC 99-CV-654 at paragraph 1. Appendix G, pg. 91.

[4]McNeil-PPC, Inc. is a company manufacturing pharmaceuticals in Pennsylvania having an SIC 2834. McNeil-PPC, Inc., was not a Delaware corporation. Division of McNeil-PPC, Inc is not a company. McNeil-PPC, Inc. is a copyright on the packaging of accused devices named above.

On June 2, 2000 **McNeil-PPC, Inc.** brought summary judgement against Allegra D. Hemphill, pro se. On March 12, 2001, the district court's ruling is partial to the corporate defendant McNeil-PPC, Inc. On March 20, 2001, Hemphill motions for reconsideration. On May 11, 2001, the district court denied Hemphill's motion. Hemphill appealed on May 23, 2001.

On appeal in the U.S. Court of Appeals for the Federal Circuit, the Federal Circuit affirmed on November 27, 2001. Appendix A, pg. 1-21. The Federal Circuit denied Rehearing on December 21, 2001. Appendix D., pg. 64-66. The mandate issued on December 28, 2001. On March 16, 2002, Allegra Hemphill respectfully petitions for writ of certiorari in the Supreme Court of the United States, within Supreme Court Rules, Rule 10.

REASONS FOR GRANTING THE WRIT

Literal patent infringement is a federal question. The reason for granting the writ of certiorari is to fulfill claim construction for the asserted claim 2, species #4, Fig. 8 and 9 in the '720 patent. The Federal Circuit did not construe all elements in claim 2 in the '720 Patent. Rule 10(a). There is no claim construction for "an outer housing" in the Federal Circuit opinion. Rule 10(c). See Appendix A, pg. 1-21.

SUPREME COURT RULE 10(a).

The Federal Circuit opinion cites: ("...it is proper for the court to use [p]rosecution history to construe the claim at issue if the prosecution history relates to the same structure **as the asserted claim**"). Alpex Computer Corp. v. Nintendo Co., 102 F. 3d. 1214, 1220. See Appendix A, pg. 10-11.

The Federal Circuit focused only on prior art

Gelardin 2393677 (the '677 patent") which has structure as 'a rotatable base by means of twisting a knob'. Appendix A, pg. 15. Statements the court relied upon regarding the Gelardin '677 patent are directed to a **non-asserted** canceled claim #3. See PL, pg. 528. The Federal Circuit did not review structure in prior art Srininvasan et.al. '567 patent. Reexamination of the '720 patent proved structure in the prior art Srininvasan '567 patent is relevant to the elected species #4, Fig. 8 and 9. Appendix E, pg. 80. This structure is readable on the **asserted claim 2.**[5]

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[5] See "an outer housing" in the '567 Patent. It is a sheet of flexible material in Col. 4, ll. 47 and Col. 5, ll. 57.

The '567 Patent has at least one layer of porous material: ("...an absorbent core 14 ... made up of any suitable absorbent material..."). ("...fluid pervious cover 16 which may be such sheet material as gauze or non-woven fabrics") Col. 4, ll. 1-5.

The '567 Patent teaches a core member: ("...may comprise a fluid impermeable sheet material such as polyethylene or polypropylene cellophane or other similar films"). Col. 4, ll. 5-12. See PL, pg. 574.

See Appendix E, pg.85 and 86. However, the Federal Circuit would not review the structure in the '567 patent: ("...does not persuade us to construe the term 'vaginal swab' to cover wrapped napkins.") See Appendix A, pg. 15.

The '720 Patent covers 'a vaginal swab' having four component parts. In a patent claim 2 that is structural ("...must have all component parts **to be** a vaginal swab") which is in accordance with the USPTO:

> ("...Srinivasan does not disclose housing means of Hemphill and does not disclose structure that could be considered the equivalent to the housing means of Hemphill."). In re Donaldson Co., 16 F.3d. 1189.)
>
> See Appendix F, pg.85-86.

Thus, if the Federal Circuit is not sure about construing the claim 2 as structural, the court should look to statements by Examiner's in the USPTO. Statements by the USPTO Examiners' are relevant for understanding the meaning and scope of claims, also. See Appendix F, pg. 80,

85-86, and pg. 89. ("statements made during reexamination "are relevant prosecution history when interpreting claims", ***quoting*** Hemphill v. McNeil-PPC, Inc. in Appendix A, on pg. 11. By the omission of statements by Examiner's in the USPTO, the Federal Circuit is gainsaying the controlling law they cited. ("It is well-settled that [p]rosecution history is relevant ...**also** for construing the meaning and scope of the claims"). Alpex Computer Corp. v. Nintendo Co., 102 F. 3d. 1214, 1220. See Appendix A, pg. 11.

Refusing to review the structure in the prior art '567 patent unfairly narrowed claim construction. Denying the "USPTO" STATEMENTS and/or Decisions about the prior art wrongfully limited the scope. Therefore, this dispute calls for the supervisory power in the Supreme Court. ("Time and again, the Supreme Court itself has resolved disputes over construction of claims as a matter of law"). Markman v. Westview Instruments, Inc. 52 F. 3d. 967 (Fed. Cir. 1995) 978. The Petitioner appeals to the Supreme Court

to exercise their authority in this matter.

SUPREME COURT RULE 10(a)

("Claim construction begins with reading the words in the claim"). Bell Comm. Research, Inc. v. Vitalink Corp. 55 F. 3d. 615, (Fed. Cir. 1995)619-620.

The word 'vaginal' is defined as:

1. Of or relating to the vagina

2. Relating to or resembling a sheath, quoting American Heritage College Dictionary , 1488 (3rd ed. 1993).[6] The patent claim 2 is structural. See as claim 2 reads:

("A vaginal swab comprising an outer housing including an inner case member and an outer case member ... "), the word "case" appears in claim 2. The word "case" is defined as:

1. a container; a receptacle. 2. a container with its contents

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[6]The word "sheath" is to encase or cover with, quoting American Heritage College Dictionary 1254 (3rd ed. 1993). PL, pg. 594.

3. A decorative or protective covering or cover (quoting the American Heritage College Dictionary 217 (3d ed. 1993). The specification describes a *container* in Col.1, ll. 66 through Col. 2, ll. 4: ("My device is comprised of an outer container,...which allow that container, or at least a part thereof, ..."). The specification also describes "the *cover* section 110 is preferably as a one-piece unit" in Col. 6, ll. 40-42. ("...the court has numerous sources that it may utilize for guidance."). Vitronics Corp. v. Conceptronic Inc., 90 F. 3d. 1576 (Fed. Cir. 1996) 1582.

The court did not observe the word "case" in claim 2 and thus, overlooks the term 'vaginal' pertaining to "an outer housing", cover or sheath in Col. 7, ll. 6-9. By choosing not to interpret the term 'vaginal' in a patent claim 2 that is structural, the Federal Circuit did not construe the term

"outer housing". [7]

SUPREME COURT RULE 10(c)

("An infringement analysis *requires* **two separate steps**. First the court must construe the claims to be infringed as a matter of law in order to establish their meaning and scope. Maxwell v. J. Baker Inc., 86 F. 3d. 1098 (Fed. Cir. 1996) 1105, A. Infringement [3-5].

The writ of certiorari should be granted because the Federal Circuit did not construe an element, "outer housing".

---

[7] "An outer housing " that is covering-over to better protect the unit is seen in Figure 8 in the '720 patent. See PL, pg. 404.
The flexible sheet as "outer housing" in the prior art '567 patent left the sides wide-open as shown in Figure 9 in the '720 patent.

("Both this court and the Supreme Court have made clear that all elements of a patent claim are material with no single part of a claim being more important or 'essential' than another"). Markman v. Westview Instruments, Inc., 52 F. 3d. 967 (Fed. Cir. 1995) 988.

Claim 2 reads: *"an outer housing including an inner case member and outer case member at least part of which is connected to and overlies said inner case member").* Col. 7, ll.6 -9.

Claim construction by the court has mistaken the term "outer housing" above, with the term "housing means" below in Col. 7, ll.11 through Col. 8, ll. 10:

"and housing means for supporting and enclosing said core member, said core member being secured to said housing means, having at least two portions movable relative to one another between first and second positions for enclosing said core member when in said first

position and for both exposing said core member and the said porous padding secured thereto and for forming a handle for said swab when in said second position.."

The fact the court is forgetting to construe "an outer housing" is evident on page 15 and certain on page 18:

('[t]he Accused Products lack an outer housing as required ...and instead have an 'outer wrapping...').

See Appendix A. The 'outer wrapping' the court disregarded, IS "an outer housing" in claim 2. Col. 7, ll. 6-9:

("with segments 126 and 128 serving to provide..."),

("can be modified as desired so that the resulting shape of segments 126 and 128 can be varied".).

("...when sections 126 and 128 are folded down...a variety of handle structures could be formed."). Col. 6, ll. 27-38. See Fig 9 in the '720 patent. PL, pg.404.

In other words, handle structures 126 and 128 (as outer housing side 1 and side 2) serves to provide

(the housing means) as band or sheet 106 . The housing means IS the handle structure required for using the swab 100. The "housing means" is "or at least a part thereof" outer housing in Col.1, ll. 68 - Col.2, ll. 4:

> (" ...which allow that container or at least a part thereof, to form the handle structure for the swab, with that handle providing both the protection for the swab while packaged and a handle during use to provide better control over swab during such use.").

"Housing means" is "a handle". "Housing means" is at, or around the base; "for supporting" the core member. Hence, on page 15 and on page 16, the Federal Circuit is actually construing the "housing means". [8] See Appendix A.

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[8] 1) "functions as a handle for the use of the swab" 2) "not designed to be removed or thrown away" 3) "to keep sticky fingers off the fibers" 4) "an annular band" 5) "an outer diameter which is at least equal to the inner diameter so that the two can fit thereby allowing the

Failure to read the words in claim 2 denies 35 U.S.C. §112. The Federal Circuit affirms: ".. core member ...secured to the outer housing", see Appendix A, pg. 16. The court is mistaken. **Claim 2 defines:** ("...core member being secured to said housing means..."). Col. 8, ll. 2-3. ("The claims are concise statements of the subject matter for which the statutory right to exclude is secured by the grant of the patent."). Multiform Desiccants, Inc. v. Medzam, LTD. 133 F.3d. 1473 (Fed. Cir. 1998) 1476. The claim defines the invention. 35 U.S.C. §112.

By granting the writ of certiorari , claim construction will be clear and consistent with the distinctions in claim 2. Claim 2 reads: *"...at least one layer of porous material secured to said core member, ...said core member being secured to said housing means ...".* Col. 7, ll. 10 - Col.

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core to be secured within the band by a suitable adhesive". See Appendix A, pg. 15 and 16.

8,ll.2. In other words, **claim 2 is <u>first defined with no extraneous property limitations</u>**. However, the Federal Circuit agreed with McNeil-PPC, Inc., extraneous property limitations from the specification are admissible. ("When the meaning of a term is sufficiently clear in the specification, that meaning shall apply."). <u>Multiform Desiccants, Inc. v. Medzam, Ltd.</u> 133 F.3d. 1473 (Fed. Cir. 1998), 1477 at [6]. See Appendix A, pg 10. In doing so, **claim 2 is not limited by** "fairly rigid core member", "annular band" or "adsorbent", but rather, <u>is inclusive of</u> the extraneous property limitations. In fact, the Federal Circuit opinion in Appendix A on page 16 affirms: ("The specification described the core member as "fairly rigid"...'). In the specification, **it is also understood**:

> "the invention is not to be limited to the disclosed embodiment but on the contrary is intended to cover various modifications and equivalent arrangements

included within the spirit and scope **of the claims,** which scope is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures."

Col 6, ll. 51-58. Therefore, structure that is <u>not</u> extraneous is first defined in the asserted claim 2. The writ of certiorari should be granted to accomplish claim construction within 35 U.S.C.§ 112.

SUPREME COURT RULE 10(c)

The four portions in a vaginal swab share equally in importance. The Federal Circuit affirms the word 'swab' via dictionary definition as: "...absorbent material *attached* to the end of a stick or wire...'. See Appendix A, pg. 12 and pg. 14. The word 'swab' in the named *vaginal swab* also reads to the unit in claim 2. See Col. 7, ll. 10 through Col.8,

ll.10. [9] The outer housing protects the unit from danger, risk **and** loss. Together, a core member, at least one layer of porous material and housing means are made safe within an outer housing side 1 and side 2. In this way, all are essential. All the portions are **secured**.

The Supreme Court is being petitioned for clarification. Claim 2 established safety and effectiveness for the unit with the words "secured to" and "secured thereto". It is not known whether or not the Federal Circuit intended to replace the words already in the claim 2 with the word "attached" via dictionary definition.

("In most situations, an analysis of intrinsic evidence alone will resolve any ambiguity in a disputed term"). ("...intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language".).

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[9]Core member and its band are "preferably" ...a one-piece unit. Col. 6, ll. 39-40.

Vitronics Corp. v. Conceptronic, Inc., 90 F. 3d. 1576 (Fed. Cir. 1996) 1582. In this way, a dictionary definition can be inclusive, but it should not limit the meaning and purpose in the claim. The word "attached" is a limitation that is not in the specification and it is not in claim 2.

> ("[W]e know of no principle of law which would authorize us to read into a claim an element which is not present, for purpose of making out a case of novelty or infringement. The difficulty is that if we once begin to include elements not mentioned in the claim in order to limit such claim and avoid a defense or anticipation, we should never know where to stop."). E.I. DuPont De Nemours & Co. v. Phillips Petro. 840 F.2d. 1430 (Fed. Cir. 1988) 1433-1434.

PUBLIC CONCERN

Upholding and maintaining the integrity in our patent system is with good reason for granting the writ of certiorari. In fact, every statement made by the patentee Hemphill was reviewed by well-qualified Examiners in the United States Patents and Trademarks Office ("the USPTO"). These examiners acutely evaluated all statements under careful scrutiny, first and before rendering their Decisions. The public trusts the record in the USPTO as a reliable source.

> "These documents have legal as well as technological content, for they show not only the framework of the invention as viewed by the inventor, but also issues of patentability as viewed by the patent examiner"). Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F. 3d. 1473 (Fed. Cir. 1998). 1477 at [5].

Therefore, in patent application 619,684, the election

of species #4 overcomes the prior art patents. See PL, pg. 534 at paragraph 4. The asserted claim 2 was not narrowed by this election. The claims readable on species #4 were claims 5 and claim 6. See PL, pg. 533. Quite simply, the asserted claim 2 in the '720 patent was claim 6 in the patent application 619,684. See PL, pg. 435. At no time, were any amendments made to claim 6. See pg. 500 and pg. 516. In fact, no amendments were made to the asserted claim 2 during reexamination.. [10] Thus, statements in the Federal Circuit opinion on page 7 and on page 12 :

> ("Hemphill narrowed her claims...and further limited the scope of her invention during two reexaminations proceedings ."), ("she narrowed her claims to overcome prior art."), ("she further limited her claims to convince the PTO to reissue...")

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[10]There is no change to the drawings. There is no change to the specification. See Appendix F, pg. 83.

are not true. The court did not look at the facts: "NO AMENDMENTS HAVE BEEN MADE TO THE PATENT AS A RESULT OF REEXAMINATION", January 26, 1999. See Appendix F, pg. 89. In other words, despite any and all statements made by the patent owner, she did not narrow claim 2 and did not limit the scope in claim 2.

PROOF / EXPLANATION

A). Claims are written for those skilled in the art. During reexamination, a sanitary napkin is the McNair 4,285,343 patent. A wrapped napkin is the Srininvasan 3,973,567 patent. Reexamination was proof claim 2 is inclusive of both "internal use" and "external use". Reexamination is proof claim 2 is not limited by the words "fairly rigid" "adsorbent" or "annular band." Proof claim 2 can be construed as structural is the fact the USPTO denied the '343 patent with no outer housing, but granted (a core

member surround by a layer of porous material with a flexible outer housing) in the '567 patent. Appendix F, pg. 77 and pg. 80.

B) The '567 patent had "after use" and "thereafter use" handling instructions. These instructions probably disgusted the court which could explain as to why this prior art '567 patent was not construed. The instructions were directed to a "used" or "dirty" wrapped napkin with three component parts like prior art '567 patent.[11] However, claim construction for the Hemphill '720 Patent should not be "prejudged" because of outrageous handling instructions in their '567 Patent. In point of fact, the three components of a "wrapped napkin" in the '567 patent dated August 1976,

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[11] Read handling instructions in prior art '567 Patent Col. 6, ll. 49-68 and Col. 7, ll. 17-35 in PL, pg. 575-576. Their "outer housing" is shown "folding-over" in Fig. 10, 11, and 14 in the '567 Patent. PL, pg. 572. Moreover, Johnson & Johnson agreed 'folding over' forms 'a handle' on accused devices; first and before reexamination in the USPTO. See Appendix H, pg. 100 and 104.

cannot cover the accused devices. The accused devices have the four component parts **to be** *'a vaginal swab'*.

In the second step of an infringement analysis, the accused "reads-on" the asserted claim 2. See PL, pg. 579-590. ("it is important the device be extremely compact, and easily manufactured so as to be both portable and disposable rendering it easily carriable and usable.") Col. 3, ll. 15-18. ("The improvements on a vaginal swab are made known through structural components to become a vaginal swab and the way the consumer makes use of the device is entirely up to them."). It is literal patent infringement.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Allegra Hemphill, *pro se*
6217 Charnwood Drive
Rockville, Maryland 20852
301 897 - 2030

Date: March 16, 2002

APPENDIX A

In the

UNITED STATES COURT of APPEALS

for the FEDERAL CIRCUIT

ALLEGRA D. HEMPHILL Plaintiff-Appellant,

v.

MCNEIL-PPC, INC., Defendant -Appellee.

No. 01-1391

DECIDED NOVEMBER 27, 2001.

Before CLEVENGER, GAJARSA, and DYK,

Circuit Judges. DYK, Circuit Judge.

NOTE: Pursuant to Fed. Cir. R. 47.6, this disposition is not citable as precedent. It is a public record. This disposition will appear in tables published periodically.

United States Court of Appeals for the Federal Circuit

ALLEGRA D. HEMPHILL Plaintiff-Appellant,

v.

MCNEIL-PPC, INC., Defendant -Appellee.

No. 01-1391

DECIDED NOVEMBER 27, 2001.

Before CLEVENGER, GAJARSA, and DYK, Circuit Judges. DYK, Circuit Judge.

Allegra Hemphill ("Hemphill") appeals the decision of the United States District Court of Maryland granting McNeil-PPC Inc.'s ("McNeil") motion for summary judgement that McNeil-s sanitary napkin products do not infringe Hemphill's U.S. Patent No. 4,557,720 (the "720

patent"). Hemphill v. McNeil-PPC, Inc., 134 F. Supp. 2d. 719 (D. Md. 2001). Because the district court properly construed the asserted claim of the '720 patent and properly determined that McNeil's sanitary napkin products do not infringe that claim as matter of law, we affirm.

BACKGROUND

Hemphill is the inventor and patentee of the '720 patent, which relates to a "Vaginal Applicator". The patent describes a disposable vaginal swab or refresher meant either to cleanse or to treat the vaginal area with fragrances, medications, germicides, or deodorants. Col. 1, ll. 34-38. The '720 patent has two independent claims, but only claim 2 is at issue on appeal. Claim 2 of the '720 patent reads as follows:

> 2. A vaginal swab comprising an outer housing including an inner case member and outer case member at least part of which is connected to and

overlies inner case member;

a core member at least one layer of porous material secured to said core member, and housing means for supporting and enclosing said core member, said core member being secured to said housing means, having at lest two portions movable relative to one another between first and second positions for enclosing said core member when in said first position and for both exposing said core member and the said porous padding secured thereto and for forming a handle for said swab when in said second position.

'720 patent, col. 7, l. 6-col.8, l.10.

McNeil manufactures and sells several families of sanitary napkin products including Stayfree sanitary napkins, Carefree, sanitary napkins. Serenity adult napkins. For purposes of determining infringement. McNeil's Stayfree, Carefree, Serenity products (the "Accuse Products") are

nearly identical in design. Hemphill, 134 F. Supp. 2d. At 723. The following description of the Accused Products is undisputed:

> The Accused [Products] are sold in multiple units in large plastic bags, inside of which are individual napkins packaged in plastic wrappers. Each of these individual units is composed of absorbent material with a flexible thin porous membrane that is attached on one side to a flexible plastic sheet that has an adhesive on the other side. In its packaging, the side of the plastic sheet containing the adhesive is attached to a thin paper sheet.
>
> In order to use the napkin, the consumer removes the plastic packaging, and peels off the thin paper sheet. Then, the consumer presses the side with the adhesive to the undergarment in order to attach the napkin to the undergarment. The napkin is intended

> to passively collect fluid during use. After use the consumer pulls on the napkin to peel it off of the undergarment, and then discards it, either directly or by first inserting the napkin into the plastic wrapper of the next napkin. The Accused [Products] are not designed to be used of placed internally in the vagina. They do not have handles, and do not have adsorbent material.

Id. At 723-34 (emphasis added) (citations omitted).

Hemphill sued McNeil in the United States District Court for the District of Maryland, alleging that several families of McNeil's sanitary napkin product lines infringe the '720 patent. McNeil moved for summary judgement of noninfringement at the close of discovery.

The district court first construed claim2 of the '720 patent. Looking to the intrinsic evidence, the district court construed the claim language in light of the specification and

prosecution history. Hemphill, 134 F. Supp. 2d. At 725-27. For example, the district court found that during the prosecution phase, Hemphill narrowed her claims to distinguish her invention from prior art. And further limited the scope of her invention during two re-examination proceedings. Id. At 721-722. On the basis of this intrinsic evidence, the district court interpreted claim 2 to require a "vaginal swab" to be used within the vaginal canal and to be comprised of four component parts: (1) an outer housing; (2) a core member; (3) at least one layer of porous material; and (4) a housing means. Id. At 728.

The district court then compared claim 2 as construed to the Accused Products, and concluded that the Accused Products, as a matter of law, did not infringe the '720 patent. Id. At 729. As for literal infringement, the district court found that "the structure of [Hemphill's] invention differs vastly from the accused devices on each element." Id. At

728. As for infringement under the doctrine of equivalents, the district court found that Hemphill "failed to offer a single assertion illustrating that the difference between the elements of her invention and the accused devices is only insubstantial. Rather, the evidence establishes [that] the difference is vast." Id. At 729.

Accordingly, the district court granted McNeil's motion for summary judgement of noninfringement . Hemphill then filed a Motion for Reconsideration pursuant to District Court of Maryland Local Rule 105.10 and Federal Rule of Civil Procedure 60 seeking reconsideration of the entry of summary judgement. The district court treated her motion as Rule 59(e) Motion to Alter or Amend Judgement, and denied the motion.

Hemphill filed a timely pro se appeal. We have jurisdiction over this appeal pursuant to 28 U.S.C. 1295 (a)(1).

DISCUSSION

I. Claim Construction

Hemphill argues that the district court improperly construed claim 2 by "reading into" claim 2 "extraneous limitations from the specification", and by reading limitations into claim 2 that relate to claim1. McNeil responds that the district court properly looked to the specification and prosecution history to construe claim 2. We agree.

In interpreting claim, a court "should look first to the intrinsic evidence of record, i.e. the patent itself, including the claims, the specification and, if in evidence the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F3d. 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). It is well-settled that for purposes of claim construction, the specification may act as a sort of dictionary that explains the invention and may define terms used in

claims. Markman v. Westview Instruments, Inc., 52 F.3d. 967, 979, 34 USPQ2d 1321, 1330 (Fed. Cir. 1995) (en banc), aff'd., 517 U.S. 370 (1996). When the meaning of a term used in a claim is sufficiently clear from its definition in the specification, that meaning shall apply. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d. 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). In this case, the district court properly looked to the specification for clarification of several terms which were not wholly defined in the claim language.

Similarly, the district court properly looked to the prosecution history of the '720 patent. Hemphill argues that "the district court construed] the wrong. .claim" by reading into claim 2 limitations relating to claim 1. But even where the prosecution history does not relate to the particular claim at issue, it is proper for the district court to use that prosecution history to construe the claim at issue if the

prosecution history relates to the same structure as the asserted claim. Alpex Computer v. Nintendo Co., 102 F.3d. 1214, 1220 40 USPQ2d 1667, 1662 (Fed. Cir. 1996) ("[W]e discern no reason why prosecution history relating to the structure of...claim 1is not pertinent to the same structure ...[in] claim 12 and 13".) It is well settled that "[p]rosection history is relevant not only for purposes of prosecution history estoppel but also for construing the meaning and scope of the claims." Id. At 1220, 40 USPQ2d at 1671. Thus, like the specification, the prosecution history can act like a dictionary, Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d. 1575, 1578, 38 USPQ2d 1126, 1129 (Fed. Cir. 1996), cert. denied, 519 U.S. 911 (1996), and statements made during reexamination proceedings "are relevant prosecution history when interpreting claims." E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d. 1430, 1439 7USPQ2d 1129, 1136 (Fed. Cir. 1988), cert.

denied, 488 U.S. 986 (1988). In this case, in construing claim 2, the district court relied on statements Hemphill made during prosecution of the '720 patent in which she narrowed her claims to overcome prior art. The district court also relied on Hemphill's statements, described below, that she made during two reexmaintion proceedings in which she further limited her claims to convince the PTO to reissue them. The district court properly relied on Hemphill's statements made during prosecution and during the reexamination proceedings, even though some of those statements related to the unasserted claim 1.

The district court construed the term "swab" to mean "a small piece of absorbent material attached to the end of a stick or wire and used for cleansing or applying medicine." Hemphill, 134 F. Supp. 2d. At 727. (Quoting American Heritage Dictionary 1810 (3d ed. 1992). Hemphill argues that the term "vaginal" does not limit her invention to a swab

meant for use inside the vaginal cavity, but instead "pertains to the outer housing as a cover or sheath". We agree with the district court. After determining that claim 2 "provides little guidance as to the terms 'vaginal' and 'swab,' the district court found that the "specification clarifies that [Hemphill] designed the 'vaginal swab' to enter into the vaginal cavity", and that the "specification defines the purpose of the invention as 'a truly portable, convenient, and disposable internal vaginal cleaning device or refresher." Id. At 726. Thus, the district court found that the specification limits the term "vaginal" to a "swab entering into the vaginal canal." Id. The district court also found that Hemphill distinguished her invention from prior art during prosecution by stating that the prior art lacked "an elongated structure for the swabbing element to be introduced into the vaginal cavity." Id. The district court accordingly precluded Hemphill from "claiming] that her invention is not meant to

enter into the vaginal cavity," and construed the term "vaginal" to mean " a swab entering into the vaginal canal". Id.

Finally, the district court relied on the following dictionary definitions to determine the plain meaning of the term "swab"; American Heritage Dictionary, 1810 (3d ed. 1992) (defining "swab" as [a] small piece of absorbent material attached to the end of a stick or wire and used for cleansing or applying medicine"); Dorland's Medical Dictionary 1617 (28th ed. 1994) (defining "swab" as "a wad of cotton or other absorbent material firmly attached to the end of a wire or stick, used for apply medication, removing material, collecting bacteriological material, etc."). The fact that the PTO granted Hemphill's request for reexamination in light of a patent for wrapped sanitary napkins (U.S. Patent No. 3,973,567) (the "Srininvasan" patent) and reissued her patent over Srininvasan does not alter the proper

construction of the term "vaginal swab," and does not persuade us to construe the term "vaginal swab" to cover wrapped sanitary napkins. We find that the district court properly construed the term "vaginal swab."

Next, the district court construed the term "outer housing" to require an outer housing that "functions as a handle for the use of the swab," and is "not designed to be removed and thrown away". Hemphill, 134 F. Supp. 2d at 727. Specifically, the district court found that during prosecution of the '720 patent, Hemphill distinguished her invention from U.S. Patent No. 2,393,677 (the '677 patent), noting that her "outer housing" transformed into a "handle structure", a metamorphosis absent from the invention of the '677 patent. Id. We find that the district court properly construed the term "outer housing."

The district court then construed the term "core member" to require "a fairly rigid core member with an

annular band or ring at its base that can fit into the band or ring of the outer housing." Id. The district court looked to Hemphill's statements during prosecution of the '720 patent to determine that the purpose of the "annular band" is "to keep sticky fingers off the fibers," and to possess "an outer diameter which is at least equal to the inner diameter" of the band attached to the outer housing, "so that the two can fit thereby allowing the core to be secured within the band by a suitable adhesive." Id. The specification described the core member as "fairly rigid," and secured to the outer housing. Id. We find that the district court properly construed the term "core member."

We agree with McNeil that the district court properly construed all terms of claim 2, as a matter of law.

II. Infringement

Hemphill's pro se appeal implicitly challenges the

district court's grant of summary judgement of noninfrignement. To prove literal infringement, Hemphill must establish that the Accused Products contain each and every limitation of the asserted claim. See e.g., Maxwell v. J. Baker, Inc., 86 F.3d. 1098, 1105, 39 USPQ2d. 1001, 1004 (Fed. Cir. 1996), cert. denied, 520 U.S. 1115 (1997). Hemphill's sole discernible argument regarding infringement is based on an advertisement describing certain features of the Accused Products. Hemphill, 134 F. Supp. 2d. At 728. After comparing claim 2 to the Accused products, the district court found that the limitations in claim 2 were not satisfied by the Accused Products.

First, as noted above, the district court found that the term "vaginal swab" limited the invention to "a small piece of absorbent material attached to the end of a stick or wire and used for cleansing or applying medicine," and meant to be used inside the vaginal canal. Id. At 727. The district

court found that the Accused Products are not designed for use within the vaginal canal, and that a sanitary napkin is neither the size nor shape to allow for internal use. Id. At 728.

Second, as noted above, the district court found that the term "outer housing" limited the invention to a swab with a housing that "functions as a handle for the use of the swab," and is "not designed to be removed and thrown away." Id. At 727. The district court found that the Accused Products lack an outer housing as required by the '720 patent, and instead have an "outer wrapping that is discarded once the sanitary napkin is utilized." Id. At 728.

Finally, as noted above, the district court found that the term "core member" required a "fairly rigid core member with an annular band or ring at its base that can fit into the band or ring of the outer housing." Id. At 727. The district court found that the Accused Products lack both a rigid core

and an annular band. Id. At 728.

We agree with the district court that no reasonable jury could find that these limitations recited in claim 2 are found in the Accused Products.

To prove infringement under the doctrine of equivalents, Hemphill must show "equivalence" between the elements of the Accused Products and the claimed elements of the '720 patent, Warner-Jenkinson, Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997, by showing that the Accused Products "perform[ ] substantially the same function in substantially the same way to obtain the same result" as the claimed elements of the '720 patent. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950). Noting that Hemphill "failed to offer a single assertion illustrating that the difference between the elements of her invention and the accused devices is only insubstantial," the district court found that "no reasonable

jury could find there to be equivalence between the elements of [Hemphill's] invention and the accused devices." Hemphill 134 F. Supp. 2d, at 729. There are simply no genuine issues of material fact regarding infringement, either literally or under the doctrine of equivalents.

III. Motion for Reconsideration

Hemphill also argues that the district court erroneously considered her Motion for reconsideration as a Rule 59(e) Motion to Alter or Amend Judgement. We do not understand how the district court's treatment of her motion as a motion under Rule 59(e) could possibly constitute prejudicial error. Because the district court's decision to treat the motion as a Rule 59(e) motion did not prejudice Hemphill, we need not further address this issue, and we affirm the district court's dismissal of Hemphill's motion.

CONCLUSION

Because the district court's claim construction was not legally erroneous, and its infringement analysis was proper, the district court's grant of summary judgement of noninfringement is

AFFIRMED.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

ALLEGRA D. HEMPHILL

v.

MCNEIL-PPC, INC.

Civil Action No. DKC 99-654

Date of Entry May 11, 2001

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

ALLEGRA D. HEMPHILL v. MCNEIL-PPC, INC.

Civil Action No. DKC 99-654

Date of Entry May 11, 2001

MEMORANDUM OPINION

Presently pending is Plaintiff Allegra Hemphill's Motion for Reconsideration brought pursuant to Federal Rule of Civil Procedure 60(b) and Local Rule 105.10. Plaintiff, proceeding *pro se,* contests this court's order issued March 12, 2001. Paper No. 60. She primarily asserts that this court erred in construing claim 2 of her patent, United States Patent No. 4,557,720. The court rejects this contention and stands by its prior ruling. Accordingly, Plaintiff's Motion for Reconsideration shall be DENIED.

Motions for reconsideration are typically treated as Rule 59(e) motions to alter or amend judgement when filed

within ten days from entry of judgement and as a Rule 60(b) motion if it is served more than ten days after the court's ruling. See *Dove v. CODESCO*, 569 F.3d. 807, 809 (4th Cir. 1978) (construing motion for reconsideration asa Rule 59(e) motion because the motion was served within ten days of entry of judgement and calls into question the correctness of that judgement; In *re Burnley,* 988 F.2d. 1,3,(4th Cir. 1992) (finding that a motion for reconsideration not filed within ten days of the entry of judgement must be construed as a motion under 60(b) rather than 59(e). In the instant case, this court entered judgement on March 12, 2001, and Plaintiff filed this motion for reconsideration on March 20, 2001, well within the ten day limit. Thus, it appears this motion is governed by Rule 59(e) rather than Rule 60(b).[1]

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[1] Even if the court construed this as a Rule 60(b) motion, it would fail. Plaintiff fails to offer any evidence supporting a basis for reconsideration as specified in Rule 60(b), such as mistake, inadvertence, excusable neglect, newly discovered evidence, or fraud. Fed. R. Civ. P. 60(b).

The Fourth Circuit has identified three grounds for amending a prior judgement pursuant to Rule 59(e): 1) to accommodate an intervening change in controlling law; 2) to account for new evidence not available at trial; or 3) to correct a clear error or prevent manifest injustice. *E.E.O.C. v. Lockheed Martin Corp.*, 116 F.3d. 110, 112 (4th Cir 1997) (citing *Hutchinson v. Staton* 994 F.2d. 1076, 1081 (4th Cir. 1993)). It is undisputed there has been no intervening change in the law and that no new evidence has been set forth. Plaintiff's primary contention is that this court erred in construing her patent claim.

Claim construction is properly a matter of law before the court. *Markman v. Westview Instruments, Inc.* 52 F.3d. 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). When construing a claim, the court examines "the claims themselves, the written description portion of the specification, and the prosecution history." *Bell & Howell*

Doc. Mgmt. Co. v. Altek Sys., 132 F. 3d. 701,705 (Fed. Cir. 1997), reh'g denied Jan. 6, 1998; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d. 1576, 1581-82 (Fed. Cir. 1996) ("The claims, specification, and file history...constitute the public record of the patentee's claim, a record on which the public is entitled to rely."). In construing claim 2, this court followed this procedure by looking at the claims themselves, the specification,, and the prosecution history.

Plaintiff contends that the court did not look to the words of the claim. However, this is simply not true as evidenced in the court's detailed opinion. Paper No. 60 at 14-18. Plaintiff also argues that the literal words of the claim should be compared to the accused devices prior to the court's construction of the claim. Courts, however, have been instructed first, to construe the claim and then, to determine whether the claim reads on the accused device. *Markman,* 52 F.3d. At 976. Thus, the court properly

construed the claim before comparing the claim to the accused devices. [2]

Additionally, a motion for reconsideration that merely revisits the same arguments already considered and rejected should be denied. *CNF Constructors, Inc. v. Donohoe Constr. Co.*, 57 F.3d. 395, 400 (4th Cir. 1995) (when "the motion seeks reconsideration of legal issues already addressed in an earlier ruling there are no grounds for relief); *Int'l Longhoremen's Assoc., AFL-CIO v. Cataneo Inc.*, 990 F.2d. 794, 801 (4th Cir. 1993) (denying motion for reconsideration brought by party "rehashing" the same

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[2] Moreover, Plaintiff's various arguments within her motion for reconsideration directly contradict each other. For example, she begins by asserting that the term "vaginal swab" was adequately defined within the words of the claim itself. Paper No. 61 at 8. She then argues that a different dictionary definition should have used in the determination of the meaning of the term "vaginal swab". Id. At 18. Finally, she claims that the term "vaginal swab" is simply a title without its own significant meaning. Id. At 20.

arguments the court had rejected). Plaintiff's motion, in large part, simply reiterates arguments this court has addressed. Consequently, this court shall DENY Plaintiff's motion for reconsideration and a separate Order will be entered.

"s/_____

DEBORAH K. CHASANOW

United States District Judge

May 11, 2001.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

ALLEGRA D. HEMPHILL

v.

MCNEIL-PPC, INC.

Civil Action No. DKC 99-654

Date of Entry March 12, 2001

APPENDIX C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

ALLEGRA D. HEMPHILL v. MCNEIL-PPC, INC.

Civil Action No. DKC 99-654

Date of Entry March 12, 2001

MEMORANDUM OPINION

Plaintiff Allegra Hemphill, proceeding pro se, alleges that Defendant Johnson & Johnson, Inc. (Johnson and Johnson) manufactures and districts products which infringe on her patent, U.S. Patent 4,557,720 ("the '720 patent"). [1] Presently pending and ready for resolution are three motions. Johnson & Johnson Consumer Companies, Inc. (JJCCI") has filed a Motion for Leave to Permissively Intervene. Defendant McNeil has filed both a Motion for Summary

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[1] On February 14, 2000, this court ordered that McNeil-PPC, Inc. ("McNeil") replace Johnson & Johnson as party defendant because McNeil is the entity responsible for the manufacture and distribution of the Stayfree, Carefree, and Serenity products at issue in this case. Paper No. 36.

Judgement for Noninfringement and a Motion to Bifurcate. [2] The issues are fully briefed and no hearing is deemed necessary. Local Rule 105.6 For the following reasons, the court shall deny JJCCI's Motion for Leave to Permissively Intervene and grant McNeil's Motion for Summary Judgement. [3]

I. Background

Ms. Hemphill filed her application for the '720 patent with the Patent and Trademarks Office ("PTO") on June 11, 1984, and her patent was subsequently issued on December 10, 1985. Paper No. 46, Ex. D1. Bearing the title "vaginal Applicator", the '720 patent describes a disposable vaginal swab or refresher meant either to cleanse or to treat the

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[2] The issue of non-infringement is the sole issue in McNeil's summary judgment motion because Defendant does not argue the validity or unenforceability of Plaintiff's patent. Paper No. 57, 2 n.2.

[3] In light of this court's decision to grant McNeil's Motion for Summary Judgement, Defendant's Motion to Bifurcate is no longer applicable, and thus, the motion will be denied as moot.

vaginal area with fragrances, medications, germicides, or deodorants. Id., Col. 1, lines 33-38. The '720 Patent has two independent claims, but only claim 2 is at issue in this litigation. Id., Ex. B. Deposition of Allegra Hemphill ("Hemphill Depo"), 10. The description contained in claim 2 of the Applicator is as follows:

> a vaginal swab comprising an outer housing including an inner case member and an outer case member at least part of which is connected to and overlies inner case member;
>
> a core member, at least one layer of porous material secured to said core member, and housing means for supporting and enclosing said core member, said core member being secured to said housing means, having at least two portions movable relative to one another between first and second positions for enclosing said core member when in said first position and for both,

exposing said core member and the porous padding secured thereto and for forming a handle for said swab when in said second position.

Id. Ex. D1, Col. 7-8, lines 1-10.

A. Prosecution of the '720 Patent.

During the prosecution phase, Plaintiff narrowed her claims to distinguish her invention from prior art cited by the Examiner. For example, Plaintiff clarified the distraction between her invention and a patent awarded to M. Alvarez by explaining that:

[t]he Alvarez device does not allow for an elongated structure for the swabbing element to be introduced into the vaginal cavity nor does it provide a sufficient handle structure.

Id., Ex. D10, PTO 00313. She also differentiated between the porous material specified in the respective patents.

Alvarez teaches that a moisture absorbent layer is

exposed after the protective covering is removed. There is a distinct difference between Absorbent and Adsorbent, to ab as in Alvarez, absorb is to take in, suck up, swallow, engross wholly, to take up or receive by chemical or actions as of gases or liquids, and to ad as in Hemphill to adsorb is to take up and hold, to gather gas or liquid or dissolved material on a surface.

Id., Ex. D6, PTO 000336 (emphasis added).

Additionally, Plaintiff distinguished the "housing" in her invention from the "housing" in the patent issued to Albert Gelardin for a Cosmetic Holder. Plaintiff noted:

[t]he Hemphill device, after removing the outer housing serves as a handle structure, and still serves as a function for the device, unlike Gelardin that states that the cover is completely removed.

Id., Ex. D6 PTO 00342.

B. Reexamination of the '720 patent

On February 2, 1998, Plaintiff asked the PTO to re-examine her patent in light of the McNair patent ("McNair") for a Sanitary Napkin. With wings. The description of the McNair patent states as follows:

The central element and side elements have fluid-impervious backing upon which is placed a thin layer adhesive which will not penetrate the absorbent materials placed thereon. The central element has a highly absorptive pad means whereas the absorptive means on the side panels may be minimal. The backing element of the central potion of the invention contains a strip of adhesive covered by a protective tape until use.

Id., ex. E2, AH 0222. Plaintiff differentiated her invention from McNair by stating that "Hemphill [vaginal swab] improves absorbing on the McNair cover sheet because of an absorbency characteristic". Id., Ex. E1, AH 0230. Thus, the McNair patent required an absorbent porous sheet, whereas

Plaintiff's patent specified adsorbent porous material.

Ultimately, the PTO denied Plaintiff's request for reexamination after finding that McNair patent "did not raise a substantial new question of patentability." Id., E4, AH 0227. Specifically, the PTO stated that the McNair patent "discloses non of the structural features recited (on Plaintiff's claims)" in light of Plaintiff's invention having a particular core member and housing. Id.

Plaintiff also applied for reexamination of her patent on May 20, 1998, this time over a patent held by Srininvasan et al. Id., Ex. F2, U.S. Letters Patent No. 3,973,567 ("the Srininvasan patent). The Srininvasan patent describes a "wrapped" sanitary napkins that includes plastic outer packaging and a napkin that affixes to an undergarment using adhesive. The patent contains this description of the invention:

A sanitary napkin having an adhesive element thereon

for attaching to an undergarment is provided with means for protecting the napkin and the adhesive element prior to use and for disposing of the napkin after use. The means comprise providing the napkin with a wrapper sheet of flexible material overlying one major surface, and the sides of the napkin and at least partially overlapping on the second major surface of the napkin. The sheet is releasably adhered to and held in place by the adhesive element.

Id., Ex. F1, PTO 00509.

The PTO granted Plaintiff's request for reexamination, finding that "[a] substantial new question of patentability affecting Claim 2" was raised by the Srininvasan patent. Id., Ex. F3, PTO 00481. Agreeing to compare claim 2 and the Srininvasan patent more closely, the PTO acknowledged the possibility that Srininvasan had the claimed structure, such as "a core member surrounded by a

layer of porous material, an outer housing, and housing means with 2 positions (one position that protects the core member and another position that exposes the core member for use)." Id.

In an effort to get her claimed reissued, Plaintiff stated the Srininvasan patent lacked both the "housing means" and "a band" at the base of the core member, found in her invention. Id., Ex. F4, PTO 00484. Plaintiff emphasized that the missing band was particularly significant to her invention because "[t]he band is the means or intermediary in both Positions from the closed location to the open state", Id., Ex. F4, PTO 00486 (emphasis in original), allowing users "to keep sticky fingers off the fibers." Id., Ex. F2, PTO 00447. Furthermore, Plaintiff distinguished her vaginal swab by stating : [i]t should be well understood that **Hemphill does not behave, operate or function like a sanitary napkin. Srininvasan does not**

have the components or parts to be a vaginal swab. Id., Ex. F2, PTO 00451. (emphasis in original.)

On January 26, 1999, the PTO issued a reexamination certificate for the '720 Patent over Srininvasan for the following reasons:

> Claim 1 of the patent to Hemphill (4557720) is considered patentable over the patent to Srininvasan, et al. (3973567) because Srininvasan simply does not disclose the claimed structure, such as an open end opposite a closed end, an annular band, and frangible seams.
>
> Claim 2 of the patent to Hemphill (4557720) is considered patentable over the patent to Srininvasan, et al. (3973567) because Srininvasan does not disclose the housing means of Hemphill and does not disclose a structure that could be considered equivalent to housing means of Hemphill. Id., Ex. Ff,

PTO 00490.

According to Defendant, beginning in 1994 and continuing for the next four years, Plaintiff sent letters to Johnson & Johnson executives alleging that the company's sanitary and adult napkins incorporate her patented technology. Specifically, Plaintiff has alleged that the Stayfree sanitary napkin, Carefree sanitary napkin , and Serenity adult napkin product lines infringe upon her patent.[4] Moreover, Plaintiff testified that she considers these respective product lines to be structurally equivalent to each other. Id., Ex. B, 363, 368, 372-74, 376077.

Defendant agrees that the three different product lines are nearly identical in design. Id., Ex. A, McCoy Decl., ¶5. Defendant has provided the following undisputed description

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[4] Although Plaintiff mentions in her deposition testimony that Band Aid brand adhesive bandage products also infringe upon her patent, she never actually argues this contention. This court construes Plaintiff's complaint as limited to products from the Stayfree, Carefree, and Serenity product lines.

of these products:

> The Accused Napkins are sold in multiple units in large plastic bags, inside of which are individual napkins packaged in plastic wrappers. (Ex. A, McCoy., ¶6). Each of these individual units is composed of absorbent material with a flexible thin porous membrane that is attached on one side to a flexible plastic sheet that has as adhesive on the other side. Id., ¶ 7. In its packaging, the side of the plastic sheet containing the adhesive is attached to a thin paper sheet. Id.,¶ 7. In order to use the napkin, the consumer removes the plastic packaging, and peels off the thin paper sheet. Id., ¶ 9. The, the consumer presses the side with the adhesive element to the undergarment in order to attach the napkin to the undergarment. Id. The napkin is intended to passively collect fluid during use. Id., ¶10. After use,

the consumer pulls on the napkin and then discards it, either directly or by first inserting the napkin into the plastic wrapper of the next napkin. Id., ¶11. The Accused Napkins are not designed to be used or placed internally in the vagina. Id.,¶12. They do not have handles, and do not have adsorbent material. Id., ¶ 13. Paper No. 46, 5.

II. Motion to Intervene

JJCCI has filed a motion for leave to permissively intervene pursuant to Rule 24(b). See Fed. R. Civ. P. 24(b). In October 1999 at her deposition, Plaintiff suggested that Band-Aid brand adhesive bandage products may also infringe upon her patent. These bandages are manufactured and/or distributed by JJCCI, another subsidiary of Johnson & Johnson, not by McNeil- the current party Defendant.

A. JJCCI's Motion for Leave to Permissively Intervene

Rule 24(b) (2) provides, in pertinent part:

> Upon timely application anyone may be permitted to intervene in an action...when an applicant's claim or defense and the main action have a question of law or fact in common...In exercising its discretion, the court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties.

Fed. R.Civ. P. 24(b)(2). Thus, permissive intervention is appropriate in circumstances in which 1) the applicant is timely; 2) the moving party's claim or defense and the main action have a common question of law or fact; and 3) the proposed intervention will not unduly delay or prejudice the adjudication of the original parties' rights. *Hill v. W. Electronic Co.*, 672 F2d. 381, 386 (4th Cir. 1982); 6 James Wm. Moore et al. *Moore's Federal Practice* § 24.10 (3ed. 1997).

B. Analysis

Although Plaintiff identify Band Aid brand adhesive bandages at her deposition taken October 18, 1999 as a product line allegedly infringing upon her patent, she never made this assertion again. Paper No. 53. Exhibit A, Hemphill Depo., 375-376. In fact, both Plaintiff's response tp JJCI's motion for leave to permissively intervene and her opposition memorandum to McNeil's motion for summary judgement contains assertions that Stayfree, Carefree and Serenity product lines are the sole product lines she is litiga6ting in this lawsuit. Paper NO. 48 at 5, Paper No. 55 at 1. Plaintiff does not assert that Ban Aid products are within the identified accused products in her complaint or in any or her papers, thus, this court will not force her to litigate an issue she has not asserted.

Moreover, JJCI provides absolutely no explanation for the eight moth time lapse between receiving notice

through Plaintiff's deposition testimony in October 1999 and filing the motion in May 2000. Plaintiff also asserts that JJCI's motion is untimely, particularly, in light of discovery closing on March 13, 2000. Thus, the court shall deny JJCI's motion for leave to permissively intervene.

II. McNeil-s Motion for Summary Judgement

A. Summary Judgement Standard

In patent cases, as well as in other cases, a motion for summary judgement will be granted only if there exists no genuine issue as to any material fact and the moving party is entitled to judgement as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Clark v. Alexander*, 85 F.3d. 146, 150 (4th Cir. 1996). The moving party bears the burden of showing that there is no genuine issue of material fact. Fed. R.Civ. P. 56(c); *Pulliam* 810 F.2d At 1286 (citing *Charbonnages de France v. Smith*

597 F.2d. 406, 414 (4th Cir. 1979)).

When ruling on a motion for summary judgement, the court must draw all reasonable inferences in favor of and construe the facts in the light most favorable to the non-moving party. *Tinsley v. First Union Nat'l Bank,* 155 F. 3d. 435, 437 (4th Cir. 1998). A properly supported motion for summary judgement may not be defeated by "the mere existence of some alleged factual dispute between the parties." *Anderson,* 477 U.S. at 247-48. Further, while the court is charged with liberally construing a complaint filed by a pro se litigant to allow the development of a potentially meritorious case, the requirement of liberal construction does not mean that the court can assume the existence of a genuine issue of material fact where none exists. *Weller v. Dep't of Social Services,* 901 F.2d. 387, 391 (4th Cir. 1990): *Beaudett v. City of Hampton,* 775 F.2d. 1274, 1277 (4th Cir 1985).

Although an infringement analysis usually involves both questions of fact and law, summary judgement of noninfringement may still be proper. *Nike Inc., v. Wolverine Worldwide Inc.* 43 F.3d. 644, 646 (Fed. Cir. 1994); *Chemical Eng'g Corp. v. Essef Indus. Inc.*, 795 F2d. 1565, 1571 (Fed. Cir. 1986). A good faith dispute about the meaning and scope of asserted claims does not, in and of itself, create a genuine dispute to preclude summary judgement in patent cases. *Lantech, Inc. v. Kelp Mach. Co.*, 32 F. 3d. 542, 546 (Fed. Cir. 1994).

B. Analysis

Plaintiff alleges that McNeil's Stayfree, Carefree and Serenity product lines literally infringe her '720 patent. Defendant objects to this characterization by stating that the original design for these products existed prior to Hemphill's patent and that these products vary in both design and

purpose compared to Hemphill's vaginal applicator. [5]

In order to assess this motion, the court must engage in a two-step infringement analysis. "The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d. 967, 979 (Fed, Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Claim construction is correctly a matter of law for the court to decide. Id. When construing a claim, a court should look to the intrinsic evidence, i.e., the patent itself, its claims, written description and the prosecution history.

---

[5] Defendant asserts that all of the accused products arise from a Stayfree sanitary napkin sold in 1981, prior to the existence of the '720 patent. See Paper No. 46. Exhibit L, Stayfree Sanitary Napkin Manufacturing Specifications. Plaintiff, however, contends that the design of these accused products changed after she sent samples of her patented invention to Defendant 's parent company in an attempt to distribute her product commercially. Without reaching the question of whether the accused products were sold in the same form prior to the filing of the '720 patent, this court will analyze whether the products in their present form infringe Plaintiff's '720 patent.

Vitronics Corp. v. Conceptronic, Inc., 90 F.3d. 1576, 1582 (Fed. Cir 1996). Additionally, statements made during the reissue [reexamination] proceeding "are relevant prosecution history when interpreting claims," *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d. 1430, 1439 (Fed. Cir. 1988).

1. Claim Construction

Claim construction begins with the words of the claim. *Bell Comm. Research, Inc. v. Vitalink Comm. Corp.*, 55 F.3d. 615, 619-620. (Fed. Cir. 1995). Moreover, claim terms are given their plain meaning unless the inventor , "choosing to be his or her own lexicographer," uses terms in a manner other than their ordinary meaning and clearly discloses these special or alternative meanings in the patent specification or file history. *Vitronics*, 90 F.3d. At 1582; *Beachwood v. Wiledwood Creative Products, Inc.*, 31 F.3d 1154, 1158 (Fed. Cir. 1994). Courts may rely on dictionary

definitions when construing claim terms "so long as the dictionary definition does not contradict any definition found or ascertained by a reading of the patent documents." *Vitronics*, 90 F.3d. At 1582.

The parties agree that only claim 2 of the '720 patent is at issue. Claim 2 provides in pertinent part as follows:

> A vaginal swab comprising an outer housing including an inner case member and outer case member at least part of which is connected to and overlies inner case member;
>
> a core member at least one layer of porous material secured to said core member, and housing means for supporting and enclosing said core member, said core member being secured to said housing means, having at lest two portions movable relative to one another between first and second positions for enclosing said core member when in said

first position and for both exposing said core member and the said porous padding secured thereto and for forming a handle for said swab when in said second position.

Plaintiff has specifically identified the four component parts to the vaginal swab as : 1) outer housing; 2) core member, 3) at least one layer of porous material; and 4) a housing means. Paper No. 46, Ex. G.

a. Vagina Swab

Plaintiff asserts that the term "vaginal" refers to the outer housing as the cover or sheath, and, "swab" refers to the unit being used as either a swab to dry or absorb or an applicator to hold or apply treatment. Paper No. 55, 3. By contrast, Defendant offers a narrower definition that a "vaginal swab" is a stick or wire with a small piece of absorbent material attached the end of it, which is of a size and structure for cleansing or applying medicine within the

vaginal canal.

While the claim provides little guidance as to the terms "vaginal" and "swab", the '720 patent specification clarifies that Plaintiff designed the "vaginal swab" to enter into the vaginal cavity. For an example, the specification defines the purpose of the invention as "a truly portable, convenient, and disposable internal vaginal cleansing device or refrehner." Paper No. 46, Exhibit F1, Col. 1, lines 46-48. Moreover, the invention in the '720 Patent is designed to dry or absorb material in the internal vaginal area. Id., Col. 3, lines 5-6. In fact, the length of the average vaginal cavity establishes the approximate length of the swab, including the core and gauze material. Id., Col. 3, lines 50-54. From the prosecution history, Plaintiff also distinguished her invention on this particular point by statement that the invention Alvarez lacked "an elongated structure for the swabbing element to be introduced into the vaginal cavity." Id., Ex.

D10, PTO 00313.

In the face of all of this evidence, Plaintiff will not be allowed to claim that her invention is not meant to enter into the vaginal cavity. After all, "a patentee may not construe a claim term one way during prosecution in order to obtain allowances of the patent and then in a different way during litigation in order to obtain a finding of infringement." *Knorr* Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp., No. CIV. A. 00-803-A, 2001 WL 179815m at 4 *4 (E. D. Va. 2001) citing *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d. 157-, 1579 (fed. Cir. 1995). Thus, the '720 patent limits the term "vaginal" to a swab entering into the vaginal canal.

As for "swab", the '720 patent states that a vaginal swab should preferably be "comprised of fairly rigid core member constructed either in segments of as a one piece unit, over which a thick gauze type absorbent pad or layer is

secured". Paper Nol. 46, Ex. D1, Col. 2, lines 5-9. The plain meaning of the term "swab" is "a small piece of absorbent material attached to the end of a stick or wire and used for cleansing or applying medicine." *American Heritage Dictionary* 1810 (3d.ed. 1992): *Dorland's Medical Dictionary* 1617 (28th ed. 1994).

B. Outer Housing & Housing Means

Plaintiff asserts that "outer housing" is the "packaging that protects [the swab] from danger, risk or loss in an enclosing or protecting relationship and the "housing means" is a part of the outer housing. Paper No. 55, 2. In claim 2, she states that the outer housing must have "an inner case member and an outer case member," must be secured to the core member and must have at least two portions movable relative to one another." Paper No. 46, D1, Col. 7-8, line 1-10. Moreover, the '720 Patent specification states that the "outer housing" is comprised of

"an external cover, an internal tubular member, and rotatable base." Id., Col. 1 lines 19-22. During the prosecution process. Plaintiff, further clarified the housing structure in order to distinguish her invention from Gelardin's patent She explained:

> [t]he Hemphill device, after removing the outer housing serves as handle structure, and still serves as a function for the device, unlike Gelardin...that states that the cover is completely removed.

Thus, the outer housing is not designed to be removed and thrown away but actually functions as a handle for the use of the swab. Plaintiff's suggestion that the outer housing is only equivalent to protective packaging is clearly at odds with both the terms of the patent as well as the Plaintiff's own assertions during the prosecution phase.

C. Core Member

Plaintiff claims that having an accused device with a

core member, whether flexible or rigid, is enough to infringe upon her patent. However, according to the'720 patent specifications, the core member should be fairly rigid, Id. , Col. 7, lines 10, and have an "annular band or ring" at the base, Id., Col. 5, lines, 31 - 33. Furthermore, the core member is secured to the outer housing "can be formed either as a solid structure preferably with a hollow interior." Id., Col. 5, lines 33-35. The purpose of the "annular band" is two-fold: 1) "to keep sticky fingers off the fiber," Id., Ex. F2. PTO 00447, and 2) to possess "an outer diameter which is at least equal to the inner diameter of the band attached to the outer housing, "so that the two can fit thereby allowing the core to be secured within the band by a suitable adhesive." Id., Ex. D1, Col. 5, line 45-48. Thus, consistent with the patent specifications, claim 2 require a fairly rigid core member with an annular band or ring at its base that can fit into the band or ring of the outer housing.

D. Layer of porous material

Plaintiff identified the layer of porous material as a critical element of her invention. Paper No. 46, Ex. G. In prior documentation, including the patent itself, Plaintiff provided a much more specified for the layer of porous material. In fact, the '720 patent specification dictates that the porous material should be "secured about the interior surface [the] core." Id., Ex. D1, Col. 5, line 35-37. Moreover, the porous material should be a "which gauze type adsorbent pad or layer." Id., Col. 2, lines 7-8. During the reexamination proceedings, Plaintiff emphasized that the absorbency of her invention distinguished it from McNair's absorbent invention. Id., Ex. E1, AH 0229 ("Hemphill improves absorbing on the McNair cover sheet because of an absorbency characteristic"). According to the patent specification and Plaintiff's previous assertions, the porous material should be secured to the exterior surface of the core

member and be composed of adsorbent material.

2. Comparison to Accused Device

After the claims are properly construed, then the terms "must be compared to the accused device or process." *Carroll Touch Inc., v. Electro Mechanical Systems, Inc* 15 F. 3d, 1573, 1576 (Fed. Cir. 1993). "In order for there to be infringement each and every limitation set forth in a patent claim must be found in the accused device, either literally or doctrine of equivalents." *Bell Atlantic Network Services v. Covad Comm. Group, Inc.* 92 F.Supp. 2d. 483, 498 (E.D. Va. 2000) (citing *Lemelson v. United States*, 752 F2d. 1538,1551 (Fed. Cir. 19985)).

a. Literal Infringement

Plaintiff offers an advertisement for the accused devices as evidence the Defendant has literally infringed her patent. The advertisement contains these assertions : 1) "an absorbent core pulls fluid-in and locks it away", and 2) "the

silky clean cover draws fluid away and helps keep it below the surface to help you feel clean and dry." Paper No. 52, Ex.2. Despite Plaintiff's attempts to portray the elements of her invention in a manner to the quoted advertisement she is unable to prove that each element of her patented invention can be found in the accused devices. A claim of literal infringement requires proof that the accused devices meet every limitation of the properly construed claims, *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F. 3d. 1473, 1476 (Fed. Cir. 1998). "If even one limitation is missing and not met as claimed, there is no literal infringement. *Mas-Hamilton Group v. LaGard, Inc.*, 156 F3d. 1206 , 1211 (Fed. Cir. 1998).

First, and foremost, Plaintiff has stated that her vaginal swab does not resemble, behave or function like a sanitary napkin. Each of the accused products is a type of sanitary napkin which lacks the rigid core required in a swab

and is not designed for use within the vaginal canal. The accused products are designed "to cover a substantial portion of an undergarment in order to passively collect fluid that flows onto them." Paper No. 46 Ex. B, ¶ 12.

Second, the structure of Plaintiff's invention differs vastly from the accused devices on each element. Plaintiff's vaginal swab is comprised of an outer housing structure that encloses a core member in first position and exposes the core member and forms a handle for the swab in the second position. The accused devices has an outer wrapping that is discarded once the sanitary napkin is utilized. At most, the discarded wrapper covers the used and soon- to- be discarded napkin. The protective packaging of the accused devices is in no way equivalent to the handle function of the "outer housing" in Plaintiff's invention.

Moreover, Plaintiff asserts that because the accused products have a core pad, they infringe upon her invention.

However, the '720 patent clearly specifies that the core member be "fairly rigid" and have an annular band at its base that can fit into the band of the outer housing. The accused products do not have such a structure.

Finally, Plaintiff went to great lengths during the reexamination phase to distinguish the absorbency characteristics of the porous material used in her invention versus the absorbeny characteristic of the McNair patent. Plaintiff, herself asserts that McNeil's products have an absorbent core yet, offers absolutely no explanation as to how the porous material can possibly be the same between Plaintiff's invention and the accused devices. Accordingly, Plaintiff has failed to establish that the accused products literally infringe upon her '720 patent.

B. Doctrine of Equivalents

Under this doctrine, a product which does not literally infringe upon the express terms of a patent may nonetheless

infringe if there is "equivalence" between the elements of the accused products and the claimed elements of the patent. *Zelinski v. Brunswick Corp.*, 185 F3d. 1311, 1316 (Fed. Cir. 1999) (citing *Warner-Jenkinson, Inc. v, Hilton Davis Chem Co.* 520 U.S. 17, 21, (1997)). Infringement occurs under this doctrine or equivalents if the difference between the particular element and the claim limitation are "insubstantial". Id. A test to determine "insubstantially" is whether "the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation." Id. At 1316-1317 (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950).

Once again, Plaintiff has admitted that her invention, a vaginal swab, "does not look or behave like a sanitary napkin" or even "function like a sanitary napkin" Paper No. 46, Ex. E3, AH 0245. Moreover, Plaintiff has failed to offer

a single assertion illustrating that the difference between the elements of her invention and the accused devices is only insubstantial. Rather, the evidence establishes the difference is vast. Accordingly, the court shall find that no reasonable jury could find there to be equivalence between the elements of Plaintiff's invention and the accused devices.

IV. Conclusion

For the foregoing reasons, this court shall GRANT McNeil's Motion for Summary Judgement for Noninfringement.

A separate Order will be entered .

"s/_____

DEBORAH K. CHASANOW

United States District Judge

March 12, 2001.

APPENDIX D

UNITED STATES COURT of APPEALS

for the FEDERAL CIRCUIT

ALLEGRA D. HEMPHILL, Plaintiff-Appellant,

v.

MCNEIL-PPC, INC., Defendant -Appellee.

No. 01-1391

Date of entry December 21, 2001.

ORDER DENYING REHEARING

UNITED STATES COURT of APPEALS

for the FEDERAL CIRCUIT

ALLEGRA D. HEMPHILL, Plaintiff-Appellant,

v.

MCNEIL-PPC, INC., Defendant -Appellee.

No. 01-1391

Date of entry December 21, 2001.

ORDER

Before CLEVENGER, GAJARSA, and DYK, Circuit Judges.

A petition for rehearing having been filed by the APPELLANT, UPON CONSIDERATION THEREOF, it is ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate of the court will issue on December 28, 2001.

FOR THE COURT

"s_____"

Jan Horbaly

Clerk

Dated: December 21, 2001

cc: Allegra Hemphill

George F. Pappas

HEMPHILL V. MCNEIL-PPC, 01-1391

(DCT -99-CV-654)

FILED

U.S. COURT OF APPEALS FOR

THE FEDERAL CIRCUIT

DEC 21 2001

JAN HORBALY

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

APPENDIX E

STATUTES

35 U.S.C.§ 102

35 U.S.C.§ 103

35 U.S.C. §112

35 U.S.C.§ 132

35 U.S.C. 102 . Conditions for patent ability; novelty and loss of right to patent

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or scribed in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he [or she] has abandoned the invention, or

(d) the invention was first patented or caused to be patented by the applicant or his [or her] legal representatives or assigns in a foreign country prior to the date of application for patent in this country on a application filed more that twelve months before the filing of the application in the

United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or

(f) he [or she] did not himself [or herself] invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other. (R.S. 4886, 4887, 4923: 35 U.S.C., 1946 ed., 31 32, 72).

Notes- Section 4(b) of the Act of July 19, 1952 provides:

"Section 102(d) of title 35, as enacted by section 1 hereof, shall not apply to existing patents and pending applications, but the law previously in effect, namely the first paragraph of R.S. 4887 (U.S. Code, title 35, sec. 32, first paragraph, 1946 ed.), shall apply to such patents and applications."

Section 4(d) of the Act of July 19, 1952 provides:

"The period of one year specified in section 102(b) of Title 35 as enacted by section 1 hereof shall not apply in the case of applications filed before August 1940, and patents granted on such applications, and with respect to such applications and patents, said period is two years instead of one year."

35 U.S.C. 103 . Conditions for patent ability' non-obvious subject matter

A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sough to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patent ability shall not be negatived by the manner in which the invention was made.

35 U.S.C. §112 Specification:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his [or her] invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his [or her] invention.

An element in a claim for combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the

specification and equivalents thereof. (R.S. 4888; 35 U.S.C., 1946 ed., 33.).

35 U.S.C. 132. Notice of rejection; reexamination

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Commissioner shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information of the propriety of continuing the prosecution of his [or her] application; and if after receiving such notice, the applicant persists in his [or her] claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention. (R.S. 4903; 35 U.S.C., 1946 ed., 51).

APPENDIX F

UNITED STATES DEPARTMENT OF COMMERCE

Patents and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE

Patents and Trademark Office

ORDER GRANTING/DENYING REQUEST

FOR REEXAMINATION

ReExamination No. 90/004,908

Date mailed 04/15/98

The request for reexamination is DENIED.

In due course, a refund under CFR 1.26(c) will be made to requester (listed below if not patent owner) by Treasury check.

ReExamination No. 90/004,908

Art Unit 3734

Decision

No substantial new question of patent ability is raised by the request for reexamination and prior art cited therein for the reasons set forth below.

The newly cited U.S. patent 4,285,343 issued to McNair does not raise a substantial new question of patent ability as to claims 1 and 2 of the requesters U.S. Patent 4,557,720 issued to Hemphill.

The claims of the Hemphill patent for which reexamination is requested , require "A vaginal swab comprised of...a pair of hinged housing segments defined by a plurality of frangible seams...in which an absorbent member is enclosed therein." And in claim 2, "a vaginal swab...including a moveable inner and outer case member;" a core member...including at least one layer of porous material

secured to a core member, and housing means for supporting and enclosing said core member, said core member being secured to said housing means, having at least two portions moveable relative to one another between first and second positions for enclosing said core member when is said first position and for both exposing said core member and the said porous material secured thereto and for forming a handle for said swab when in said second position."

The U.S. patent to McNair discloses none of the structural features recited, supra. Further, the McNair patent is neither relevant under 35 U.S.C. 102 nor U.S.C. 103. Accordingly, since the newly submitted prior art McNair presents no substantial new question of patent ability, the request for reexamination is DENIED.

J. Yasko:lf

("s/_____)

703 308-2986

April 3, 1998

UNITED STATES DEPARTMENT OF COMMERCE

Patents and Trademark Office

ORDER GRANTING/DENYING REQUEST

FOR REEXAMINATION

Serial Number 90/004987

Patent under reexamination : 4,557,720

Date mailed 07/06/98

Art Unit 3735

The request for reexamination has been considered.

Identification of the claims, the references relied on, and the rationale supporting the determination are attached.

Attachment(s); PTO-892.

The request for reexamination is GRANTED.

A substantial new question of patent ability affecting claim 2 of United States Patent Number 4,557,720 is raised by the request for reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1,136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550 (a)). Extensions of time in reexamination proceedings are provided for in 37 CFR 1,550(c).

The request for re-examination indicates that the patent to Srininvasan Et al. . (39735567) may be relevant to claim 2 and the examiner feels that further consideration of

this reference is warranted as it was not considered during prosecution of patent #4,557,720. The request also presents arguments as to why claim 2 is patent able over the patent to Srininvasan et al. . (3973567).

It is agreed that the reference to Srininvasan et. al. raises a substantial new question of patent ability with respect to claim 2. Srininvasan et al.., has structure that may read on claim 2 such as a core member surrounded by a layer of porous material, an outer housing, and housing means with 2 positions (one position that protects the core member and another position that exposes the core member for use). For these reasons the examiner considers that there is a substantial new question of patent ability with respect to claim 2 versus the patent to Srininvasan et. al.

("s/_____)

John G. Weiss

Supervisory Patent Examiner

Group 3700

D.R. (Initials)

Assistant Examiner, Sector 3700

Notice of References Cited

Document 3,973,567

Date 8-1976

Srinvasan et al.

Class 604

Subclass 386

UNITED STATES DEPARTMENT OF COMMERCE

Patents and Trademark Office

NOTICE OF INTENT TO ISSUE

REEXAMINATION CERTIFICATE

Examination has been terminated in this reexam proceeding and a certificate will be issued in due course in view of patent owner's communication filed on 7/14/98; 7/11/98 and 7/24/98.

The Reexamination Certificate will indicate the following::

Change in the Specification : No

Change in the Drawings: No

Status of the Claims : Patent claims confirmed 1,2.

Note attached statements of reasons for patentabilityand/or confirmation. Any comments considered necessary by patent

owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submissions should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation".

("s/_____)

John G. Weiss

Supervisory Patent Examiner

Group 3700

cc. Requestor

Re-exam no. 90/004987 Date mailed 10/07/98

Art Unit 3735

1. STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentabiility and/or confirmation of the claims found patent able in this reexamination proceeding:

Claim 1 of the patent to Hemphill (4557720) is considered patent able over the patent to Srininvasan et al. (3973567) because Srininvasan simply does not disclose the claimed structure, such as an open end opposite a closed end, an annular band, and frangible seams.

Claim 2 of the patent to Hemphill (4557720) is considered patent able over the patent to Srininvasan et al. (3973567) because Srininvasan does not disclose the housing means of Hemphill and does not disclose structure that could be considered equivalent to the housing means of Hemphill.

In re Donaldson Co., 16 F.3d. 1189, 29 USPQ2d 1845 (Fed. Cir. 1994).

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of reasons for Patent ability and/or Confirmation " and will be placed in the reexamination file.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dennis Ruhl whose telephone number is (703) 308-22-62.

("s/_____)

Johnson G. Weiss

Supervisory Patent Examiner

Group 3700

D.R. (Initials)September 1, 1998

REEXAMINATION CERTIFICATE (3712th)

United States Patent [19]

Hemphill

[54] **VAGINAL APPLICATOR**

[76]Inventor Allegra D. Hemphill, 6217 Charnwood Dr., Rockville, Md. 20852

Reexamination Request: No. 90/004.987. May 22, 1998

Reexamination Certificate for:

Patent No. **4,557,720**

Issued: **Dec. 10. 1985**

Appl. No. **619,684**

Filed: **Jun. 11, 1984**

Related U.S. Application Data

[62] Division of Ser. Bo. 434,828 Oct. 18, 1982, abandoned.

051] Int. Cl. A61B 10/00

[11] **B1 4,557,720**

[45] Certificate Issued **Jan. 26,1999**

[52] U.S. Cl. 604/1; 401/77; 401/78

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,973,567 8/1976 Srininvasan et al. 604/386

Primary Examiner -John Weiss

[57] **ABSTRACT**

A disposable vaginal refresher or swab comprised of an outer container for enclosing an inner, fairly rigid core member about which an adsorbent layer is secured. The outer container when removed exposes the adsorbent covered member or allows that member to be moved out of the container into an operable position. The outer container also forms the handle of the disposable swab element.

B1 4,557,720

REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

NO AMENDMENTS HAVE BEEN MADE TO THE PATENT AS A RESULT OF REEXAMINATION.

IT HAS BEEN DETERMINED THAT:

The patentability of claims **1** and **2** is confirmed.

* * * * *

APPENDIX G

JOHNSON & JOHNSON'S MOTION

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MARYLAND

SOUTHERN DIVISION

ALLEGRA D. HEMPHILL Plaintiff,

v.

JOHNSON & JOHNSON , Defendant

Civil Action No. DKC 99CV654

Date: June 4, 1999

DEFENDANT JOHNSON & JOHNSON'S

MOTION TO SUBSTITUTE DEFENDANT

Defendant Johnson & Johnson, by its undersigned attorneys, moves to dismiss Johnson & Johnson a party to the instant lawsuit, and moves to substitute McNeil-PPC, Inc., and for reason states as follows:

1. In her Complaint and discovery responses, plaintiff Allegra D. Hemphill ("Hemphill) has alleged that various products infringe upon United States Patent No. 4,557,720, her patent for a vaginal applicator. Although her theories of infringement remain obscure and difficult to comprehend, the brand name products she has accused of infringement are Stayfree®, Serenity®, Sure & Natural®, and Carefree® sanitary napkins. These products are not manufactured, marketed or sold by Johnson & Johnson. They are products of a different company called McNeil-PPC, Inc.

2. Johnson & Johnson, the original party Defendant, the parent company of McNeil-PPC, Inc is a Delaware corporation with its principal place of business in New Jersey. McNeil-PPC, Inc., a subsidiary of Johnson & Johnson, is also a Delaware corporation with its principal place of business in New Jersey.

3. At all times material hereto, McNeil-PPC, Inc was and is subject to jurisdiction in the courts of the state of Maryland.

4. Accordingly, defendant Johnson & Johnson requests that McNeil-PPC, Inc be substituted as the correct party defendant in this case. Plaintiff will not be prejudiced by this substitution since McNeil-PPC, Inc waives any defects in service arising out of the incorrect designation.

Respectfully submitted,

("s/_____)
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Terri L. Turner

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Johnson & Johnson and
McNeil-PPC, Inc.

APPENDIX H

JOHNSON & JOHNSON LEGAL ANALYSIS /OPINION

JOHNSON & JOHNSON

Office of General Counsel

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New Brunswick, N.J. 08933-7003

Tel. (732) 524-2826

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January 6, 1998

Johnson & Johnson

Office of General Counsel

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Fax: (732) 524-2808

January 6, 1998

This is in response to your letters of December 11,23,29 to the Chief Executive Officer of Johnson & Johnson.

We have carefully reviewed your allegation that McNeil-PPC's STAYFREE Maxi sanitary napkin infringes claim 2 of your U.S. Patent No. 4,557,720, in particular the opinion letter of April 29, 1997 from Mr. Sheldon H. Parker from the law firm of Parker and DeStephano. While we disagree with your as well as Mr. Parker's opinion regarding

the scope of your patent and its relevance to our STAYFREE sanitary napkins, we have nevertheless provided you with an analysis (as Mr. Parker has interpreted the claims) of a sanitary napkin having an outer wrapper which was disclosed in our U.S. Patent No. 3,973,567 (copy enclosed). Our patent issued more than one year prior to the filing date of your patent application. As you will note, all of the elements (in accordance with Mr. Parker's interpretation) which you allege exist in our present STAYFREE sanitary napkin are also disclosed in this earlier patent. Thus, to the extent that you allege that our current STAYFREE sanitary napkins read on the claims in your patent, these claims cannot be considered to be valid.

CLAIM 2

A vaginal swab comprising an outer housing including an inner case member and outer case member at least part of which is connected to and overlies inner case member

STAYFREE**

plastic wrapper side one side two

U.S. PATENT 3,973,567

sheet 20 of flexible material side one and side two

CLAIM 2

a core member, at least one layer of porous material secured to said core member and housing means for supporting and enclosing said core member, said core member being secured to said housing means

STAYFREE

inner pad with absorbent core

cottony dry cover of STAYFREE

'567 PATENT

absorbent core 14 with fluid pervious cover to core via envelope formed with cover 16 and fluid impermeable sheet

CLAIM 2

having at least two portions movable relative to one another

between first and second positions

STAYFREE

fold over STAYFREE unit as for disposal .

'567 PATENT

fold over napkin unit

CLAIM 2

for enclosing said core member when in said first position

STAYFREE

as for disposal

'567 PATENT

Figures 10, 11, 14 show ends folded over for disposal

CLAIM 2

and for both exposing said core member and the said porous padding secured thereto and for forming a handle for said swab when in said second position

STAYFREE

folded over for disposal forms handle for disposal

'567 PATENT

folded over for disposal forms handle for disposal

Figures 10, 11 and 14 show ends folded over for disposal

***Hemphill interpretation of STAYFREE

The following is an alternate comparison of the product and CLAIM 2.

A vaginal swab comprising an outer housing including an inner case member and outer case member at least part of which is connected to and overlies inner case member

STAYFREE

outer housing

inner porous sheet

'567 PATENT

outer housing

fluid pervious cover 16

CLAIM 2

and outer case member at least part of which is connected to

and overlies inner case member

STAYFREE

outer plastic layer

'567 PATENT

fluid impermeable sheet overlying bottom major surface

CLAIM 2

a core member, at least one

layer of porous material secured to said core member

STAYFREE

inner absorbent pad cottony dry cover STAYFREE.....

'567 PATENT

Absorbent core 14 with fluid pervious cover 16 secured to

core via envelope formed with cover 16 and fluid

impermeable sheet

CLAIM 2

and housing means for supporting and enclosing said core member ,

STAYFREE

outer shell

'567 PATENT

outer shell

CLAIM 2

said core member being secured to said housing means having at least two portions movable relative to one another between first and second positions

STAYFREE absorbent core is secured to cottony dry layer and to plastic layer

'567 PATENT

absorbent core 14 is secured to core via envelope formed by fluid pervious cover and fluid impermeable sheet

CLAIM 2

for enclosing said core member when in said first position

STAYFREE

fold over two ends of STAYFREE unit as for disposal

'567 PATENT

Figures 10, 11, 14 show ends folded over for disposal

CLAIM 2

and for both exposing said core member and the said porous padding secured thereto and for forming a handle for said swab when in said second position

STAYFREE

folded over for disposal forms handle for disposal

'567 PATENT

folded over for disposal forms handle for disposal

**Hemphill interpretation of STAYFREE

We have carefully considered and addressed all of the

issues raised in your letters and have now provided you with a copy of the Johnson & Johnson patent which issued before Hemphill, as you requested. Accordingly, as we previously advised, our STAYFREE sanitary napkins do not infringe any valid claim of your patent and we consider this matter to be closed.

We note from your correspondence that you are now represented by legal counsel. Since the current matter concerns legal issues, it would be unethical for us to continue to correspond directly with you. Accordingly, in the unlikely event that you have any further questions or issues regarding the foregoing claim analysis, please direct these to your attorney and we will be happy to discuss these issues with him.

Sincerely,

("s/_____")

James P. Barr

JPB

Enclosure

cc. Sheldon Parker